

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOZORB DEVICE PRODUCTS
LIABILITY LITIGATION

This Order Relates to the Following Case:

No: 1:23-cv-10260

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Civil Action No. 1:22-cv-11895-ADB

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Before the Court is Plaintiffs' Amended Motion for Leave to File Amended Complaint, [ECF No. 263].¹ For the following reasons, that motion is **DENIED**.

Because Plaintiffs seek to amend their complaint after the deadline for amendments to pleadings has passed, "Rule 16(b)'s more stringent good cause standard" applies rather than "Rule 15(a)'s leave freely given standard." United States ex rel. D'Agostino v. EV3, Inc., 802 F.3d 188, 192 (1st Cir. 2015); see also Fed. R. Civ. P. 16(b)(4) ("A schedule may be modified only for good cause and with the judge's consent."). The good-cause standard "focuses on the diligence (or lack thereof) of the moving party more than it does on any prejudice to the party-opponent." Steir v. Girl Scouts of the USA, 383 F.3d 7, 12 (1st Cir. 2004); see also Amyndas

¹ Plaintiffs initially moved for leave to amend their complaint on May 27, 2025, [ECF No. 260], filing the instant amended motion to amend three days later, on May 30, 2025, [ECF No. 263]. Plaintiffs' filing of their amended motion mooted their prior motion to amend, see [ECF No. 265], but the Court in ruling on the amended motion considers the arguments Plaintiffs made in the memorandum they filed in support of their prior motion, [ECF No. 260-1].

Pharms., S.A. v. Zealand Pharma A/S, 48 F.4th 18, 37 (1st Cir. 2022) (“When a party has allowed a ‘considerable period of time’ to elapse, it must ‘show some valid reason for [its] neglect and delay.’” (quoting Hayes v. New England Millwork Distributors, Inc., 602 F.2d 15, 20 (1st Cir. 1979))). Moreover, “[w]here the motion to amend is filed after the opposing party has timely moved for summary judgment, a plaintiff is required to show ‘substantial and convincing evidence’ to justify a belated attempt to amend a complaint.” Steir, 383 F.3d at 12 (quoting Resolution Tr. Corp. v. Gold, 30 F.3d 251, 253 (1st Cir. 1994)); see also Hatch v. Dep’t for Child., Youth & Their Fams., 274 F.3d 12, 19 (1st Cir. 2001) (“If . . . leave to amend is not sought until after discovery has closed and a summary judgment motion has been docketed, the proposed amendment must be not only theoretically viable but also solidly grounded in the record.”).

Plaintiffs have not shown good cause to allow their proposed amendments. Plaintiffs sought leave to amend on May 30, 2025, [ECF No. 263], a year and a half after the December 1, 2023 deadline for filing amended pleadings, see [No. 23-cv-10260, ECF No. 13 at 5; ECF No. 14], and have not provided a “valid reason for [their] neglect and delay,” Amyndas Pharms., 48 F.4th at 37 (citation omitted). Plaintiffs state that their proposed amendments are a “direct response to the Court’s prior ruling, which applied the law of the state in which each Plaintiff resides to assess the viability of their respective claims,” [ECF No. 260-1 at 2], in reference to the Court’s March 14, 2025 decision denying Hologic’s motion to dismiss the design defect claims alleged by Plaintiffs in their amended complaints, [ECF No. 234]. That March 2025 decision, which itself predated Plaintiffs’ instant motion by two-and-a-half months, was not, however, the Court’s first articulation of the applicable choice-of-law principles. The Court made its choice-of-law approach clear in its September 26, 2024 summary-judgment decision,

more than eight months before Plaintiffs filed their instant motion to amend. See [ECF No. 170 at 14–19]. And the Court cannot help but note that the fact that Massachusetts law would not govern should have been evident from the outset. In any event, Plaintiffs’ delay here is considerably greater than that in Torres-Alamo, the only authority Plaintiffs cite in the body of their motion. See Torres-Alamo v. Puerto Rico, 502 F.3d 20, 25–26 (1st Cir. 2007) (reversing denial of motion to amend and finding no undue delay where plaintiff’s motion to amend was filed “only six months after she filed her complaint and less than two months after [the defendant] had filed its answer”). Beyond the issue of timing, Plaintiffs have offered no explanation as to why their amendments are necessary to “conform to the [C]ourt’s [March 2025] ruling,” [ECF No. 260-1 at 4], and little explanation as to why they are now seeking to amend, including what the consequences of the proposed amendments might be in terms of discovery or proof.

In that regard, the Court is not convinced that permitting an amendment at this stage would not unduly prejudice Hologic. Plaintiffs equivocate on the impact of their proposed amendments, stating both that they “do not . . . fundamentally alter the theory of the case” and that the Court’s choice-of-law framework “materially impacts the causes of action available to each Plaintiff, the elements of those claims, and the potential relief.” [ECF No. 260-1 at 2, 4]. Under the circumstances, with discovery complete and summary-judgment motions pending for at least some of Plaintiffs, the Court is not persuaded that an amendment that adds an entirely new theory of relief—strict liability—would not prejudice Hologic. See Steir, 383 F.3d at 12.

Accordingly, Plaintiffs’ motion for leave to file an amended complaint, [ECF No. 263], is **DENIED**.

SO ORDERED.

August 11, 2025

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE